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| 10/614,105 | 07/08/2003 | Isao Yamazaki | KAS-187 | 7653 | |
| 24955 97591 978922008 MATTINGLY, STANGER, MALUR & BRUNDIDGE, P.C. 1800 DIAGONAL ROAD | | | EXAM | EXAMINER | |
| | | | TURK, | TURK, NEIL N | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Application No. Applicant(s) 10/614,105 YAMAZAKI ET AL. Office Action Summary Examiner Art Unit NEIL TURK 1797 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 14 April 2008. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1.3-5 and 7-9 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) _____ is/are allowed. 6) Claim(s) 1,3-5 and 7-9 is/are rejected. 7) Claim(s) _____ is/are objected to. 8) Claim(s) _____ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) ☐ The drawing(s) filed on 08 July 2003 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. Attachment(s) 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s)/Mail Date. Notice of Draftsperson's Patent Drawing Review (PTO-948)

Information Disclosure Statement(s) (PTO/S5/08)
 Paper No(s)/Mail Date ______.

5) Notice of Informal Patent Application

6) Other:

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DETAILED ACTION

Remarks

This Office Action fully acknowledges Applicant's remarks filed on April 14th, 2008. Claims 1, 3-5, and 7-9 are pending. Claims 2, 6, and 10-12 have been cancelled.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3-5, and 7-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear what is meant by the recitation with respect to the controller, that recites, "...controlling...said moving mechanism at each of predetermined continuous cycles, including controlling...so that only one of said plurality of dispensing probes...sucks a reagent...within a same cycle of said predetermined continuous cycles." It is unclear how the controller is controlling the moving mechanism and dispensing probes such that it is unclear what is meant by the recitation "at each of predetermined continuous cycles". Examiner asserts that a continuous cycle may be interpreted as endless and thereby the recitation to the control of the single dispensing probe being used within a same cycle is unclear and indefinitely recited. Does Applicant intend to claim a certain cycle in which a control is carried out with one of the plurality of dispensing probes and then another cycle is initiated with

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respect to another, and different one of the plurality of dispensing probes? And so forth...in a continuous fashion with respect to different dispensing probes?

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior at are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
The factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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Claims 1, 3-5, 8, and 9 are rejected under 35 U.S.C. 103(a) as obvious over Ohishi et al. (6,019,945), hereafter Ohishi, in view of Ginsberg et al. (4,234,538), hereafter Ginsberg.

Ohishi discloses a sample analysis system. Ohishi shows in figure 3 a controlled (connected to computer 6b and control unit 40) analysis unit 3B in which there are a plurality of reagent disks 26a, 26b. Ohishi also shows a plurality of reagent dispensing probes 8a, 8b arranged to suck reagent from one of the reagent containers (12a, 12b). and inject the reagent into one of the reaction cells 46b (within reactor section 5b). Examiner further asserts that the reagent dispensing probes are arranged to inject reagent from the reagent container into the reaction cell arranged at the same position of the reaction disk such that the reagent dispensing probes may be swiveled (also vertically movable; the moving mechanism encompassing the pipetter nozzle, shaft, and structural connections allowing for such swiveling and vertical movement) to place reagent in the same reaction cell 46 at the same position (lines 23-67, col. 6; lines 1-13. col. 7, fig. 3). With regard to claim 4, Ohishi disclose several units (3A, 3C, 3D, 3E, 3F, and 3G) with such elements for performing single analyses. With regards to claims 5 and 8, Applicant has not positively recited a rail extending over the reagent disks, and the railing is not established as an element of the device, the claims only recite an intended use for the moving mechanism, and intended uses are not afforded patentable weight.

If the reagent dispensing probes are not taken to be arranged to inject reagent sucked from the respective reagent container into the reaction cell arranged at the same

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dispensing position for of the reaction disk, then it would have been obvious to modify Ohishi. It would have been obvious to modify Ohishi to the above functional arrangement so that both reagents could be added to the same reaction cell at the same position on the reaction disk so that the reaction disk would not have to move to different positions for the first and second reagents to be added. This configuration would be an obvious modification so as to avoid unwanted mixing and reacting of the contents in the reaction cell 46b that could occur in the movement of the reaction disk to a second position for further reagent.

Ohishi does not disclose including reagent dispensing probes arranged at a single disk.

Ginsberg discloses an automatic analyzer that includes first and second reagent dispensers 44, 46 arranged about a reagent disc 42 (abstract; lines 20-32, col. 5, fig. 1).

Such that Ohishi discloses a plurality of reagent dispensing probes 8a, 8b arranged at each of the reagent disks 26a, 26b, it would have been obvious to modify Ohishi to include a reagent dispensing probes arranged at a single disk, such as taught by Ginsberg. It would have been obvious to modify Ohishi to include reagent dispensing probes arranged at a single disk such as taught by Ginsberg in order to provide a second available, and clean dispensing probe that is available for immediate use on the next progression.

One of ordinary skill in the art would also apply the inclusion of dispensing probes to the second reagent disk of Ohishi in a likewise fashion in order to provide a

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second available, and clean dispensing probe that is available for immediate use on the next progression.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ohishi in view of Ohishi in view of Ginsberg as applied to claims 1, 3-5, 8, and 9 and in further view of Minekane (4.808.380).

Ohishi/Ginsberg does not disclose at least one reagent disk arranged inside a reaction disk.

Minekane discloses an automatic chemical analyzing apparatus. Minekane discloses a cuvette rotor 18 in which cuvettes are mounted in an annular array to receive sample and reagent to be then analyzed by a photometer (reaction disk with reaction cells). Minekane further discloses reagent supply 14, which has a pair of coaxial reagent rings 24 and 26, and is placed peripherally within the ring of cuvette arrays (arranged inside the reaction disk) (lines 19-67, col. 2, fig. 1).

It would have been obvious to modify Ohishi/Ginsberg to arrange reagent disks inside the reaction disk such as taught by Minekane in order to save space and optimize the workspace area.

Response to Arguments

Applicant's arguments filed April 14th, 2008 have been fully considered but they are not persuasive. With regards to claims 1, 3-5, 8, and 9 rejected under 35 USC

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102(b) as being anticipated by, or in the alternative under 35 USC 103(a), as being obvious over, Ohishi et al. (6,019,945), Applicant traverses the rejection.

Applicant argues that Ohishi fails to disclose the moving mechanism, or the controller that controls the reagent dispensing probes, wherein only one of the reagent dispensing probes arranged at each reagent disk sucks a reagent from a reagent container of said each reagent disk within a same cycle. Examiner asserts that Ohishi does disclose such elements. Ohishi discloses a controlled analysis system in figure 3 (connected to computer 6b and control unit 40, for executing required processing and control of the system, which includes the movement of the reagent and reaction disks: see, for example, lines 31-50, col. 4+) in which such a system includes movable dispensing probes 8a, 8b operatively connected in the device, and thereby their movement (swiveling or vertical movement) is included in the automated control functions of the system. Examiner further asserts that the moving mechanism is constituted by the pipetter nozzle, shaft, and structural arrangement connected to the dispensing probes 8a, 8b that allow for swiveling and vertical movement of them between the reagent disks and reaction disks. Further, as discussed above, the control with respect to the single dispensing probe during a same cycle of said predetermined continuous cycles is indefinitely recited. Examiner asserts that Ohishi does disclose such a control function with the dispensing probe and corresponding reagent disk. Examiner asserts that Ohishi discloses controlling the plurality of reagent dispensing probes and said reagent disks so that only one of said plurality of dispensing probes arranged at a reagent disk sucks a reagent from a reagent container of the disk within a

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same cycle, as disclosed, for example, in lines 54-67+, col. 6+. Examiner asserts that even as the second reagent is added from dispensing probe 8b after the first reagent has been added and the reaction cuvette mixed, such addition of the second reagent is said to be within the same predetermined continuous cycle, as both first and second reagent are necessary for the assay.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NEIL TURK whose telephone number is (571)272-8914. The examiner can normally be reached on M-F, 9-630.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jill Warden/ Supervisory Patent Examiner, Art Unit 1797

NT